IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

DEANNA K. RENYER and DAVID W. BLOIR,	**Case No.: 08-CV-1343-JMR/FLN**
Plaintiffs,	
v.	**DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO PLAINTIFFS' COMPLAINT**
PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC,	
Defendants.	**Jury Trial Demanded**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia") and G.D. Searle LLC ("Searle") and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Celebrex® (celecoxib) ("Celebrex®") and Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Celebrex® and Bextra®.

II.
ORIGINAL ANSWER

Response to Introduction

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe

drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that that Celebrex® or Bextra® are defective or unreasonably dangerous, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Celebrex and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that Pfizer does business in the State of Minnesota. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors

in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® and Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by

law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants deny the allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that

Plaintiffs claim that the parties are diverse and the amount in controversy exceeds $75,000, exclusive of interests and costs.

12. Defendants admit that Pfizer and Pharmacia are registered to do business in the State of Minnesota. Defendant admits that Pfizer and Pharmacia maintain a registered agent in the State of Minnesota. Defendants admit that Pfizer, Pharmacia, and Searle may be served through their registered agents. Defendants deny the remaining allegations in this paragraph of the Complaint.

13. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

14. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny that Celebrex® or Bextra® caused Plaintiffs injury or damages and deny the allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct, deny committing a tort in the States of Minnesota or Kansas, and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their

approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

17. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations and, therefore, deny the same.

18. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations and, therefore, deny the same.

19. Defendants admit that the FDA approved Celebrex® on December 31, 1998. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

20. Defendants admit that Searle submitted a New Drug Application ("NDA") for parecoxib sodium on September 11, 2000, for the management of acute pain in adults and for opioid sparing. Defendants state that parecoxib sodium is an injectable form of valdecoxib. Defendants

admit that the FDA denied the application for parecoxib sodium in July 2001. Defendants deny the remaining allegations in this paragraph of the Complaint.

21. Defendants admit that a NDA for Bextra® was filed with the FDA on January 15, 2001. Defendants deny the remaining allegations in this paragraph of the Complaint.

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid

arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants deny the allegations in this paragraph of the Complaint.

27. Defendants admit that a labeling revision for Bextra® was issued on November 24, 2004. Defendants state that the revised Bextra® label speaks for itself and respectfully refer the Court to the revised Bextra® label for its actual language and full text. Any attempt to characterize the revised Bextra® label is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that the revised Bextra® label speaks for itself and respectfully refer the Court to the revised Bextra® label for its actual language and full text. Any attempt to characterize the revised Bextra® label is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants admit that the sale of Bextra® was voluntarily suspended in the United States market as of April 7, 2005. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and full text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no

response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

32. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

33. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

34. Defendants state that the allegations in this paragraph of the Complaint regarding "other pharmaceutical companies" are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the

cyclooxygenase-1 (COX-1) isoenzyme." Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

36. Defendants admit that Searle submitted a New Drug Application ("NDA") for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,

which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

43. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

44. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that the FDA Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is

denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

56. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Defendants admit that there was a clinical trial called APC. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is

denied. Plaintiffs fail to provide the proper context for the allegations concerning "Data Safety Monitoring Board" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

60. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

61. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide the proper context for the allegations concerning "other Celebrex trials" contained in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. As for the allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

63. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

64. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the

Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced studies speak for themselves and respectfully refer the Court to the studies for their actual language and text. Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the

remaining allegations in this paragraph of the Complaint.

68. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

70. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that allegations in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants deny the allegations in this paragraph of the Complaint.

73. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

74. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

75. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

77. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph

of the Complaint.

79. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

81. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

82. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

83. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

85. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

the Complaint.

88. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants deny the allegations in this paragraph of the Complaint.

90. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

93. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

96. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the

remaining allegations in this paragraph of the Complaint.

Response to Plaintiffs' Individual Statements of Facts

98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants deny any wrongful conduct, that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® caused Plaintiff injury or damages and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants deny any wrongful conduct, that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Strict Liability

104. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

105. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

106. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved

prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® are defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® are defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® and Bextra® were expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

109. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® are defective, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

110. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Breach of Implied Warranty of Merchantability

111. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

112. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

113. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex® and Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

116. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action:
Breach of Implied Warranty of Fitness for a Particular Purpose

118. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

119. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

120. Defendants deny the allegations in this paragraph of the Complaint.

121. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that

they provided FDA-approved prescribing information regarding Celebrex® and Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

122. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

123. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

125. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach Express Warranty

127. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

128. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex® and Bextra®. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

129. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Negligence

130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and Bextra®, and, therefore, deny the same. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any

wrongful conduct, deny that Celebrex® or Bextra® are defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

132. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Demand For Judgment

Answering the unnumbered paragraph of the Complaint headed "Demand For Judgment Against Defendants Pfizer, Inc.; Pharmacia Corporation; and G.D. Searle LLC (FKA G.D. Searle & Co.)," Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

III.
GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® and Bextra® are prescription medical products. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® and Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drugs in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® and Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drugs were manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex® or Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® and Bextra® are prescription medical products, available only on the order of a licensed physician. Celebrex® and Bextra® provided adequate warnings to Plaintiffs' treating and prescribing physicians.

Thirteenth Defense

13. The products at issue were not in a defective condition or unreasonably dangerous at the time they left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® and Bextra® were at all times material to the Complaint reasonably safe and reasonably fit for their intended use and the warnings and instructions accompanying Celebrex® and Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for their approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® and Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Celebrex® or Bextra® by persons other than Defendants or persons acting on their behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex® and Bextra®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex® and Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical products at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical products referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical products at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical products within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® and Bextra® are prescription pharmaceutical drugs and fall within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical products at issue "provide[] net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State of Kansas, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Kansas law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota and Kansas. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate

advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex® and Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the products' use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® and Bextra® were designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not

having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® and Bextra® were not unreasonably dangerous or defective, were suitable for the purpose for which they was intended, and were distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® and Bextra® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the products complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® and Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® and Bextra® outweighed their risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® and Bextra® are comprehensively regulated by the FDA pursuant to the Federal Food, Drug, & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should

be used in the labeling accompanying Celebrex® and Bextra®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Plaintiffs' claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

Fifty-sixth Defense

56. Defendants state that to the best of their knowledge, information, and belief, reasonable discovery will likely produce evidentiary support demonstrating that the fault of others for whom Defendants are not responsible directly caused or contributed to Plaintiffs' injuries, and the fault of Plaintiffs and such others should be compared pursuant to K.S.A. § 60-258(a).

Fifty-eighth Defense

57. Plaintiffs' claims are barred by Defendants' compliance with relevant legislative and administrative regulatory safety standards authorized by the Kansas Product Liability Act, K.S.A. §§ 60-3301, et seq.

Fifty-ninth Defense

58. To the extent Plaintiffs contend that Plaintiffs are entitled to damages pursuant to a personal injury claim, which contention is expressly denied, claims for non-economic losses may not exceed $250,000 pursuant to K.S.A. § 60-19a.

Sixtieth Defense

59. Plaintiffs' claims against Defendants are barred by K.S.A. § 60-3306.

Sixty-first Defense

60. Plaintiffs' claims against Defendants are limited by K.S.A. § 60-1903.

Sixty-second Defense

61. Defendants state that any award of punitive damages in this case would violate Defendants' procedural and substantive due process rights because there are insufficient circumstances in this case to support the reasonableness of an award of punitive damages and there are inadequate legal and procedural constraints imposed on the fact finder's discretion to impose such awards. The standard for punitive damages in Kansas lack sufficient objective criteria and procedural safeguards to give a jury adequate criteria or an appropriate range of proportionality regarding punitive damages.

Sixty-third Defense

62. Defendants state that it would violate Defendants' rights guaranteed by the United States Constitution and the Kansas Constitution to impose punitive damages against them which are penal in nature by requiring a burden of proof on Plaintiffs which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases. In the alternative, entitlement to such damages would be provided by a "clear" and "convincing" standard of proof, in view of insufficient substantive and procedural protections under Kansas law regarding punitive damages.

Sixty-fourth Defense

63. Plaintiffs' claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

Sixty-fifth Defense

64. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.
JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants pray that Plaintiffs take nothing by their suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which it may be justly entitled.

Dated: June 4, 2008.

FAEGRE & BENSON LLP

s/ Joseph M. Price

Joseph M. Price, # 88201
Erin M. Verneris # 0335174
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
T (612) 766-7000
F (612) 766-1600

Attorneys for Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC